UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

PAULA D. ANDREWS,	§	MDL DOCKET NO. 2782
	§	
	§	CASE NO. _____
Plaintiff,	§	
	§	COMPLAINT FOR PERSONAL
vs.	§	INJURIES AND DAMAGES
	§	
JOHNSON & JOHNSON and ETHICON, INC.,	§	
	§	
Defendants.	§	DEMAND FOR JURY TRIAL

PLAINTIFF'S ORIGINAL COMPLAINT

NATURE OF THE CASE

1. This is a products liability tort case. Plaintiff Paula D. Andrews developed serious and potentially life-threatening injuries caused by the surgical implantation of the Physiomesh™ Flexible Composite Mesh Device (Physiomesh) to treat a ventral hernia from which she suffered.

2. Physiomesh is manufactured by Defendant Johnson & Johnson (J&J) and its subsidiary Ethicon, Inc. (Ethicon). Both J&J and Ethicon were responsible for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion and/or distribution of the Physiomesh that caused Plaintiff Andrews's injuries.

3. After Plaintiff's Physiomesh implant, Defendants J&J and Ethicon voluntarily recalled the product implanted in her.

4. As a result of having the J&J/Ethicon Physiomesh implanted in her, Plaintiff has experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical treatment and corrective surgery and hospitalizations, and suffered additional economic damages.

5. Plaintiff Andrews's lawsuit against Defendants J&J and Ethicon asserts claims and seeks damages for negligence; strict product liability for design defect; strict product liability for failure to warn; strict product liability for manufacturing defect; breach of implied warranty; and a violation of the Missouri Merchandizing Practices Act, V.A.M.S § 407.020 *et seq.* Plaintiff Andrews also seeks punitive damages.

JURISDICTION AND VENUE

6. At the time of implant, Plaintiff Paula D. Andrews was a resident of the Eastern District of Missouri. Plaintiff currently resides in the State of Michigan. Defendant Johnson & Johnson and its wholly owned subsidiary Defendant Ethicon, Inc., are foreign corporations with their principal places of business in a state other than the states of Missouri or Michigan.

7. The Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332. The amount in controversy as to each Defendant exceeds the sum of $75,000, exclusive of costs and interest, and the action is between citizens of different states.

8. Venue of this case is appropriate in the Eastern District of Missouri as the events and omissions giving rise to Plaintiff's causes of action occurred in substantial part in the Eastern District of Missouri. Plaintiff states that, but for the Order permitting direct

filing into the Northern District of Georgia pursuant to Practice and Procedure Order No. 2, Plaintiff would have filed in the Eastern District of Missouri, Eastern Division. Therefore, Plaintiff respectfully requests at the time of transfer of this action back to the trial court for further proceedings, that this case be transferred to the above-referenced District Court.

THE PARTIES

Plaintiff

9. At the time of implant, Plaintiff Paula D. Andrews was a resident and citizen of the State of Missouri. Plaintiff is currently a resident of the State of Michigan.

Defendants

10. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08993.

11. Defendant Ethicon, Inc., is a New Jersey corporation with its principal place of business located at PO Box 151, Somerville, New Jersey 08876.

FACTUAL ALLEGATIONS

12. On September 9, 2011, Dr. Kareem D. Husain implanted a Physiomesh Device (Product Code PHY2025V) laparoscopically into Paula Andrews to treat her ventral hernia. The surgery took place at Barnes-Jewish Hospital in St. Louis, Missouri.

13. Plaintiff Andrews's condition was not remedied by the laparoscopic procedure. In fact, her condition became steadily worse with persistent abdominal pain, dysuria, and recurrent urinary tract infections.

14. On April 23, 2014, Paula Andrews was admitted to Barnes-Jewish Hospital in St. Louis, Missouri for recurrent urinary tract infections and dysuria. Dr. Jairam R. Eswara surveyed Plaintiff Andrews's bladder and found that the Physiomesh had eroded into her bladder. Dr. Eswara found and removed a "foreign body greenish in hue" at the dome of her bladder and "what appeared to be an epithelialized band of bladder mucosa" from Plaintiff Andrews's bladder.

15. On March 14, 2016, Paula Andrews was admitted to Detroit Medical Center, Harper University Hospital in Detroit, Michigan to remove the Physiomesh that was infected and had eroded into her bladder and to treat the vesicocutaneous fistula that formed as a result of the defective Physiomesh device. The surgeon described the procedure to excise the infected mesh as "tedious and painstaking," noting that the mesh "stuck very heavily on the dome of the bladder," and came out in "multiple pieces."

16. Defendants J&J and Ethicon were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the hernia mesh product.

17. Among the intended purposes for which Defendants J&J and Ethicon designed, manufactured and sold Physiomesh was use by surgeons for hernia repair surgeries. That was the purpose for which the Physiomesh was implanted in Plaintiff Paula D. Andrews.

18. Defendants represented to Plaintiff and her physicians that their Physiomesh was a safe and effective product for hernia repair.

19. Defendants' Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components, including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

20. Physiomesh has a unique design incorporating five distinct layers: two layers of polyglecaprone-25 (Monocryl) film covering two underlying layers of polydioxanone film (PDS), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States.

21. The multi-layer coating was represented and promoted by J&J and Ethicon to prevent or minimize adhesion and inflammation, and to facilitate incorporation of the mesh into the body. But the multi-layer coating did not do so. Instead, it prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response, resulting in an adverse tissue reaction that included migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue, and improper healing.

22. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation and other complications.

23. The multi-layer Physiomesh coating provides a breeding ground for bacteria, in which the bacteria cannot be eliminated by the body's immune response. Thus, infection is allowed to proliferate.

24. The multi-layer coating of the J&J and Ethicon Physiomesh is cytotoxic, immunogenic, and not biocompatible. The coating therefore causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

25. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

26. The polypropylene mesh portion of the Physiomesh was insufficient to withstand normal abdominal forces, resulting in recurrent hernia formation and/or rupture and deformation of the mesh itself.

27. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, causing damage to organs, and potential fistula formation.

28. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff Paula Andrews.

29. Neither Plaintiff Andrews nor her implanting physician was adequately warned or informed by J&J or Ethicon of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff Paula Andrews nor her implanting physician was adequately warned or informed by J&J or Ethicon of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

30. The Physiomesh implanted in Plaintiff Paula Andrews failed to reasonably perform as intended. The mesh caused serious injury and had to be surgically removed via invasive surgery, and necessitated additional invasive surgery to repair the hernia that the Physiomesh was initially implanted to treat.

31. Plaintiff Paula Andrews's severe adverse reaction, and the necessity for surgical removal of the Physiomesh, directly and proximately resulted from the defective and dangerous condition of the product and defective and inadequate warnings by Defendants J&J and Ethicon about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff Andrews has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

32. In May of 2016, J&J and Ethicon issued a notice entitled "Urgent: Field Safety Notice," relating to its Physiomesh Flexible Composite Mesh—the same product implanted in Plaintiff. They sent such notification to hospitals and medical providers in

various countries worldwide. In their safety notice, Defendants advised the providers of "a voluntary product recall" of Physiomesh Flexible Composite Mesh. The recall cited two international device registries reporting data reflecting recurrence/reoperation rates after laparoscopic placement as higher than that observed from a data set relating to patient outcomes after implantation with other mesh.

33. But J&J and Ethicon failed to issue a nationwide recall in the United States, opting instead to simply remove the product from shelves and cease further sales within the United States.

CLAIMS FOR RELIEF

1. NEGLIGENCE

34. Plaintiff realleges all previous paragraphs.

35. Although Defendants J&J and Ethicon had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training, and preparing written instructions and warnings for Physiomesh, they failed to do so.

36. Defendants knew, or in the exercise of reasonable care should have known, that the Physiomesh Flexible Composite Mesh Device was defectively and unreasonably designed and/or manufactured, and was unreasonably dangerous and likely to injure patients like Plaintiff Andrews in whom Physiomesh was implanted. They also knew or should have known that Plaintiff Andrews and her physicians were unaware of the dangers and defects inherent in the Physiomesh.

37. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, training and preparing written instructions and warnings for Physiomesh, Plaintiff Paula Andrews suffered injuries and damages as summarized in this Original Complaint.

2. STRICT LIABILITY: DESIGN DEFECT

38. Plaintiff realleges all previous paragraphs.

39. At the time the Physiomesh was implanted in Plaintiff Paula Andrews, the mesh product was defectively designed. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Further, Defendants J&J and Ethicon failed to design against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

40. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff Andrews in the condition in which the product was sold.

41. The implantation of Physiomesh in Plaintiff was medically reasonable, and was a type of use that Defendants J&J and Ethicon intended and foresaw when they designed, manufactured and sold the product.

42. The risks of the Physiomesh design significantly outweigh any benefits that Defendants contend could be associated with the design. The multi-layer coating, which is not used in any other hernia mesh product sold in the United States, prevents tissue from incorporating into the mesh, leading to encapsulation, deformation, scarification and contraction, migration, erosion and rejection. Additionally, the impermeable multi-layer coating of the Physiomesh leads to seroma formation, provides a breeding ground for

infection, and protects bacteria from being eliminated by the body's natural immune response.

43. The multi-layer coating of the Physiomesh, which was marketed, promoted and intended as a barrier against adhesion to the internal organs, was only temporary; it was expected and intended to degrade over time inside the body. Thus, the coating prevented tissue ingrowth in the short term, and degraded in the long-term, eventually leaving the "naked" polypropylene mesh exposed to the internal viscera and tissues. The degradation of the multi-layer coating caused or exacerbated an intense inflammatory and foreign body reaction. Once exposed to the viscera, the polypropylene mesh will inevitably adhere to the viscera, initiating a cascade of adverse consequences. Any purported beneficial purpose of the multi-layer coating (to prevent adhesion to the internal viscera and organs) was non-existent. The product provided no benefit, while substantially increasing the risks to the patient.

44. The polypropylene mesh within the defective multi-layer coating of the Physiomesh was itself dangerous and defective, particularly when used in the manner intended by Defendants in the Physiomesh. When implanted adjacent to the intestines and other internal organs—as Defendants intended for Physiomesh—polypropylene mesh is unreasonably susceptible to adhesion, bowel perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

45. The polypropylene mesh used in the Physiomesh device was insufficient in strength to withstand the internal forces of the abdomen after implantation, which made

the device susceptible to rupture and/or deformation. That occurred with the Physiomesh implanted in Plaintiff Andrews.

46. The appropriate treatment for complications associated with Physiomesh involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to the patient. Plaintiff Paula Andrews underwent additional invasive surgery.

47. Physiomesh was designed and intended for intraperitoneal implantation, which involved the product being implanted in contact with the intestines and/or other internal organs. The contact unnecessarily increased the risks of adhesion, erosion, fistula formation, and other injuries.

48. At the time the Physiomesh was implanted in Plaintiff, the warnings and instructions provided by J&J and Ethicon for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

49. At the time the Physiomesh was implanted in Plaintiff Andrews, there were safer feasible alternative designs for hernia mesh products that would have prevented the injuries she suffered.

50. The Physiomesh product costs significantly more than competitive products because of its unique multi-layer coating, even though the multi-layer coating provided no benefit to consumers, and increased the risks to patients implanted with these devices.

51. The Physiomesh implanted in Plaintiff Andrews failed to reasonably perform as intended and had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair. Thus, it provided no benefit to her.

52. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff Paula Andrews suffered injuries and damages as summarized in this Original Complaint.

3. STRICT LIABILITY: FAILURE TO WARN

53. Plaintiff realleges all previous paragraphs.

54. At the time the Physiomesh was implanted in Plaintiff Andrews, the warnings and instructions Defendants J&J and Ethicon provided for the Physiomesh were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers, and failed to provide adequate warnings and instructions concerning these risks.

55. Defendants expected and intended the Physiomesh product to reach users such as Plaintiff in the condition in which the product was sold.

56. Plaintiff Andrews and her physicians were unaware of the defects and dangers of Physiomesh, and were unaware of the frequency, severity, and duration of the defects and risks associated with the Physiomesh.

57. Defendants' Instructions for Use (IFU) provided with the Physiomesh expressly understated and misstated the risks known to be associated specifically with the

Physiomesh. The IFUs stated that "Potential adverse reactions are those typically associated with surgically implantable materials." But no other surgical mesh sold in the U.S.—and no other "surgically implantable material"—suffers the same serious design flaws as Physiomesh. And no other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications. Those complications include prevention of mesh incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh.

58. The Physiomesh IFU failed to adequately warn Plaintiff Andrews's physicians of numerous risks which J&J and Ethicon knew or should have known were associated with the product. They include the risk of the Physiomesh's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, or rupture of the mesh.

59. J&J and Ethicon failed to adequately warn Plaintiff Andrews or her physicians about the necessity for invasive surgical intervention in the event of complications. Defendants also failed to train the physicians on how to properly treat such complications when they occurred.

60. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

61. J&J and Ethicon represented to physicians, including Plaintiff Andrews's physicians, that the multi-layer coating would prevent or reduce adhesion. They expressly intended for the Physiomesh to be implanted in contact with the intestines and internal organs and marketed and promoted the product for that purpose. But Defendants failed to warn them that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device. They further failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier. Thus, when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

62. With respect to the complications listed in their warnings, J&J and Ethicon provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with Physiomesh were more frequent and severe, and lasted longer than those with safer feasible alternative hernia repair treatments.

63. If Plaintiff Andrews or her physicians had been properly warned of the defects and dangers of Physiomesh, and of the frequency, severity and duration of the risks associated with the Physiomesh, she would not have consented to allow the Physiomesh to

be implanted in her body, and her physicians would not have implanted the Physiomesh in Plaintiff.

64. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff Paula Andrews suffered injuries and damages as summarized in this Original Complaint.

4. STRICT LIABILITY: MANUFACTURING DEFECT

65. Plaintiff realleges all previous paragraphs.

66. The Physiomesh contained a manufacturing defect when it left the possession of J&J and Ethicon. The Physiomesh differs from their intended result and/or from other ostensibly identical units of the same product line.

67. The manufacturing defects in the Physiomesh were a producing cause of Plaintiff Andrews's injuries and damages specified in this Original Complaint.

5. BREACH OF IMPLIED WARRANTY

68. Plaintiff realleges all previous paragraphs.

69. At the time Defendants J&J and Ethicon designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted and distributed the Physiomesh for use by Plaintiff Andrews, they knew of the intended use of the Physiomesh, and impliedly warranted their product to be of merchantable quality, and safe and fit for its intended use.

70. When the Physiomesh was implanted in Plaintiff to treat her hernia, the Physiomesh was being used for the ordinary purposes for which it was intended.

71. Plaintiff, individually and/or by and through her physicians, relied upon Defendants' implied warranties of merchantability in consenting to have the Physiomesh implanted in her.

72. Contrary to such implied warranties, the Physiomesh was not of merchantable quality, and was not safe and/or was not fit for its intended use. The Physiomesh was unreasonably dangerous and unfit for the ordinary purposes for which it was used. Defendants J&J and Ethicon failed to warn of known or reasonably scientifically knowable defects in the Physiomesh.

73. As a direct and proximate result of the conduct of Defendants J&J and Ethicon, Plaintiff Paula Andrews suffered the injuries and damages described in this Original Complaint.

6. VIOLATION OF MISSOURI MERCHANDIZING PRACTICES ACT, § 407.020 *et seq.*

74. Plaintiff realleges all previous paragraphs.

75. As alleged in this Original Complaint, the conduct of Defendants constitutes unfair or deceptive acts or practices in trade or commerce as defined in, and in violation of the Missouri Merchandizing Practices Act, V.A.M.S. § 407.020 et seq.

76. The conduct of Defendants impacted the public interest, had the capacity to deceive a substantial portion of the public, and, in fact, did deceive Plaintiff Andrews.

77. As a direct and proximate result of these unfair or deceptive acts or practices, Plaintiff has been damaged in an amount to be determined with specificity at trial.

78. As a direct and proximate result of these unfair or deceptive acts or practices, Plaintiff has been damaged in an amount to be determined with specificity at trial.

79. Plaintiff seeks both compensatory and punitive damages, and pursuant to V.A.M.S. § 407.025.1, the Plaintiff is entitled to reasonable attorneys' fees incurred in prosecuting this action.

7. PUNITIVE DAMAGES

80. Plaintiff realleges all previous paragraphs.

81. Defendants J&J and Ethicon failed to adequately test and study the Physiomesh to determine and ensure that the product was safe and effective before releasing it for sale for permanent human implantation; and they continued to manufacture and sell Physiomesh after obtaining knowledge and information that the product was defective and unreasonably unsafe.

82. Even though Defendants have other hernia repair mesh devices that do not present the same risks as the Physiomesh Flexible Composite Mesh Device, they developed, designed and sold Physiomesh, and continued to do so, because the Physiomesh has a significantly higher profit margin than other hernia repair products. Defendants J&J and Ethicon were aware of the probable consequences of implantation of the dangerous and defective Physiomesh, including the risk of failure and serious injury, such as suffered by Plaintiff Andrews. They willfully and recklessly failed to avoid those consequences, and in doing so, acted intentionally, maliciously and recklessly with regard to the safety of those persons who might foreseeably have been harmed by the Physiomesh product, including Plaintiff Paula Andrews, justifying the imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Paula D. Andrews seeks judgment against Defendants Johnson & Johnson and Ethicon, Inc., jointly and severally, as follows:

1. economic and non-economic damages in an amount in excess of $75,000 as to each Defendant, as provided by law and to be supported by the evidence at trial;
2. an award of attorneys' fees and costs of suit, as allowed by law; and
3. such other legal and equitable relief as this Court deems just and proper.

JURY DEMAND

Plaintiff Paula D. Andrews requests a trial by jury.

Dated: September 12, 2017

Respectfully submitted,

/s/ Kelsey L. Stokes

Kelsey L. Stokes (TX Bar No. 24083912)
kelsey_stokes@fleming-law.com
George M. Fleming (TX Bar No. 07123000)
george_fleming@fleming-law.com
Gregory D. Brown (TX Bar No. 24078266)
gregory_brown@fleming-law.com
FLEMING, NOLEN & JEZ, L.L.P.
2800 Post Oak Blvd., Suite 4000
Houston, Texas 77056-6109
Tel: 713-621-7944
Fax: 713-621-9638

Attorneys for Plaintiff